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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,996

05/24/2007

Mariko Fujimura

0071-0647PUS1

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

NOTIFICATION DATE

DELIVERY MODE

08/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/587,996	Applicant(s) FUJIMURA ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The IDS filed on August 1, 2006 is recorded and acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: separation step to separate the labeled specific binding materials which are not bound with the analyte. Without this separation step, all the magnetic particles would give off signal including the ones that do not have analyte bound thereto and thus there would be false positive magnetic signals.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Josephson et al. (US PGPub. 2003/0092029 A1).

Josephson teaches a composition comprising binding moieties linked to a magnetic particle. The binding moieties cause a specific interaction with a target molecule (see [58]) via functionalized polymer such as polyethylene glycol (see [24] and [61]). The particles have sizes about 20-200 nanometers (equivalent to 0.02 – 0.2 micrometer). (see [63]). For claims 2-4, Josephson teaches that polymer is polyethylene glycol or polysaccharides and derivatives (see [24] and [61]). Regarding the number of repeat units, since Josephson teaches the same polymer as the present invention, such polymer must have repeat units within the same range as claimed in the present invention. For claim 6, Josephson teaches that the binding moieties are antibodies and the target analytes are antigen (see [78]). For claim 8, Josephson teaches a method of detecting a target comprising contacting such composition described above with a sample and the magnetic resonance (magnetic signal) is detected. (see [83] and [84]). Josephson teaches immobilizing polymer such as polysaccharide to the particles via biotin-avidin complex. In this embodiment, the polysaccharide has reactive ends which are biotinylated and then is exposed to avidin linked nanoparticles (see [119], [130]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson et al. (US PGPub. 2003/0092029 A1), as applied to claim 1-4, 6 and 8, and in view of Foster (US 4,444,879).

Josephson has been discussed above but fails to teach that the polyethylene glycol is bound to the magnetic particle via a biotin-avidin complex and packaging the composition described above into a kit.

Foster teaches packing assay reagents into a kit with instruction. (see col. 15, fig. 6).

For claim 5, although, Josephson does not explicitly teaches attaching polyethylene glycol to the surface of a magnetic particles via biotin-avidin complex, Josephson teaches a method of immobilizing a polysaccharide to a nanoparticle, such polysaccharide is used the same way as the polyethylene glycol, as a spacer or linker to bind the binding moiety to the nanoparticle. (see discussion above). Thus, one of ordinary skills in the art would be motivated to immobilize the polyethylene glycol to the nanoparticle via a biotin-avidin complex as the polysaccharide.

For claim 7, it would have been obvious to one of ordinary skills in the art to pack the reagents used in the assay taught by Josephson into a kit as taught by Foster for advantage of economic convenience and long-term storage.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641
August 11, 2008

/Mark L. Shibuya, Ph.D./
Supervisory Patent Examiner, Art Unit 1641